FEB 2 2 2006

K053604

WaveLight®

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter:	WaveLight Laser Technologie, AG Am Wolfsmantel 5 91058 Erlangen Germany
Contact Person:	Alexander Popp Am Wolfsmantel 5 91058 Erlangen Germany Telephone: +49 (0)9131-6186-121 Fax: +49 (0)9131-6186-202
Summary Preparation Date:	November 14, 2005

2. Names

Device Name:	IDAS
Classification Name:	Laser Instrument, Surgical Powered Product Code: GEX Panel: Dermatology and Plastic Surgery

3. Predicate Devices

The IDAS laser system is substantially equivalent to the Laserscope laser system AURA (K951034).

4. Device Description

The IDAS laser system (532 nm) is used for the treatment of superficial vascular lesions and for pigmented lesions.
The laser radiation emitted by this type of laser system has a wavelength of 532 nm. Radiation of this wavelength is characterized by a particularly strong absorption by hemoglobin and melanin. The radiation emitted by the laser penetrates into the human skin 0.1 – 1 mm thus being able to locally heat up even deeper-lying target structures which consequently leads to the desired effect.

The laser system (532 nm) can be used in two different operating modes: In the "cw" (= continuous wave) mode or in the "pulsed" operating mode.

Beam transmission is ensured by a fiber and a handpiece with different adapters which are used to adjust the spot diameter on the skin. Beam transmission, however, can be also effected via a bare fiber.

While the parameter wavelength is specified by the device, spot size, fluence or power, pulse duration, frequency and the intensity of the aiming beam can be selected by the treating physician for optimal adjustment to individual requirements.

5. Indications for Use

The IDAS laser system is intended for use for
Aesthetics:
vascular lesions, spider veins, spider naevi, teleangiectasis, red superficial veins of the legs and face, pigmented lesions (e.g. café-au-lait stains, lentigo), hemangiomas, port wine stains, rosacea.

6. Performance Data

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2 2006

WaveLight Laser Technologie AG
c/o Mr. Jeffrey D. Rongero
Underwriters Laboratories, Inc.
12 Laboratory Drive
PO Box 13995
Research Triange Park, North Carolina 27709-3995

Re: K053604
Trade/Device Name: IDAS Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 2, 2006
Received: February 6, 2006

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

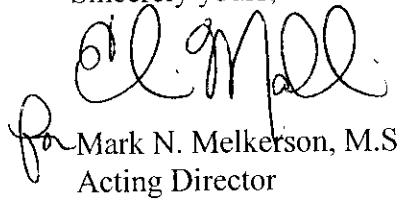
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson, M.S.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WaveLight®

510 (k) Indications for Use

Indications for Use

510(k) Number (if known): N/A
Device Name: IDAS

Indications for Use: K053604

The IDAS laser system is intended for use for
Aesthetics:
vascular lesions, spider veins, spider naevi, teleangiectasis, red superficial veins of the legs and face, pigmented lesions (e.g. café-au-lait stains, lentigo), hemangiomas, port wine stains, rosacea.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___N/A___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053604